

Subject: FR Notice Comments - 73FR1360 - LLNA Peer Panel Meeting

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Below is the result of your feedback form. It was submitted by
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Comments: Looking at the very detailed work that has been done on reviewing potency assessments in the LLNA, I am moved to observe that we have here a wealth of information which indicates that relative human potency can be assessed well. The scientific PRP needs to keep in mind that toxicologists working on just about all other endpoints have very much less data. Despite this, decisions on safe exposure limits are made, on a daily basis, for endpoints such as chronic tox etc, solely based on thresholds observed in rat feeding studies (or similar), where there is no validation, no correlation with human effects/potency etc., and if these were subjected to the type of rigorous review being applied to the LLNA, all of them would, without question, fail dismally. Despite limitations, the LLNA offers a good step forward in assessing skin sensitisers. Good toxicologists are those who understand the limitations of an assay, as well as its strengths.
